

**ANSWER AND COUNTERCLAIMS OF DEFENDANTS  
LUPIN PHARMACEUTICALS, INC. AND LUPIN, LTD.**

1. On information and belief, Lupin admits the allegations set forth in paragraph 1 of the Complaint.

2. On information and belief, Lupin admits the allegations set forth in paragraph 2 of the Complaint.

3. On information and belief, Lupin admits the allegations set forth in paragraph 3 of the Complaint.

4. On information and belief, Lupin admits the allegations set forth in paragraph 4 of the Complaint.

5. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 5 of the Complaint.

6. Lupin admits that Lupin Pharmaceuticals, Inc. is a Virginia corporation, and the wholly-owned subsidiary of Lupin Ltd. Lupin admits that Lupin Pharmaceuticals, Inc. has a principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st floor, Baltimore, Maryland 21202. Lupin admits that Lupin Pharmaceuticals, Inc. distributes generic drugs for sale and use in the United States. Lupin denies that Lupin Pharmaceuticals, Inc. distributes numerous generic drugs. Lupin denies that Lupin Pharmaceuticals, Inc. manufactures generic drugs and to the extent there are any remaining allegations in paragraph 6 of the Complaint, Lupin denies them.

7. Lupin admits that Lupin Ltd. is an Indian corporation having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Lupin admits that Lupin Ltd. manufactures generic drugs for sale and use in the United States, but denies that Lupin manufactures numerous generic drugs for sale and use in the United States. Lupin admits that Lupin Pharmaceuticals, Inc is a wholly-owned

subsidiary of Lupin Ltd.. Lupin denies that Lupin Pharmaceuticals, Inc. manufactures generic drugs and to the extent there are any remaining allegations in paragraph 7 of the Complaint, Lupin denies them.

8. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 8 of the Complaint.

9. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 9 of the Complaint.

10. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 10 of the Complaint.

11. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 11 of the Complaint.

12. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 12 of the Complaint.

13. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 13 of the Complaint.

#### **NATURE OF THE ACTION**

14. On information and belief, Lupin admits the allegations set forth in paragraph 14 of the Complaint.

**JURISDICTION AND VENUE**

15. Lupin admits that this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§1331 and 1338(a).

16. Lupin does not contest that this Court has personal jurisdiction over Lupin Ltd. and Lupin Pharmaceuticals, Inc. Lupin is without knowledge or information sufficient to form a belief as to the Court's personal jurisdiction over the other Defendants. Lupin denies that it has committed, or aided, abetted, contributed to and/or participated in the commission of, any tortious act or any act of patent infringement. Lupin is without knowledge or information sufficient to form a belief as to any act of patent infringement committed by other Defendants in the Complaint. To the extent there are any remaining allegations in paragraph 16 of the Complaint, Lupin denies them.

17. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 17 of the Complaint.

18. Lupin does not contest that this Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. and to the extent there are remaining allegations in paragraph 18 of the Complaint, Lupin denies them.

19. Lupin does not contest that this Court has personal jurisdiction over Lupin Ltd. and to the extent there are remaining allegations in paragraph 19 of the Complaint, Lupin denies them.

20. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 20 of the Complaint.

21. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 21 of the Complaint.

22. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 22 of the Complaint.

23. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 23 of the Complaint.

24. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 24 of the Complaint.

25. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 25 of the Complaint.

26. Lupin does not contest that venue is proper in this judicial district. To the extent there are remaining allegations in paragraph 26 of the Complaint, Lupin denies them.

#### **THE PATENT-IN-SUIT**

27. Lupin admits that United States Patent No. 5,061,703 (“the ‘703 patent”), titled “Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia,” was issued by the United States Patent and Trademark Office (“PTO”). Lupin further admits that the issue date set forth on the face of the ‘703 patent is October 29, 1991 and the assignee on the face of the ‘703 patent is Merz + Co. GmbH & Co. Lupin denies that the ‘703 patent was “duly and legally” issued by the PTO. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 27 of the Complaint, and, therefore, denies them.

28. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegation made in paragraph 28 of the Complaint that Forest is the exclusive licensee of the '703 patent. Upon information and belief, Lupin admits that Forest holds New Drug Application ("NDA") No. 21-487 for Namenda® brand memantine hydrochloride tablets. Upon information and belief, Lupin admits the '703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Namenda®, but denies that it is properly listed. To the extent there are remaining allegations in paragraph 28 of the Complaint, Lupin denies them.

29. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 29 of the Complaint.

30. On information and belief, Lupin admits the allegations set forth in paragraph 30 of the Complaint.

**Count I – Infringement Of The '703 Patent By Defendant Cobalt**

31. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 31 of the Complaint.

32. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 32 of the Complaint.

33. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 33 of the Complaint

34. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 34 of the Complaint

35. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 35 of the Complaint

36. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 36 of the Complaint.

**Count II – Alleged Infringement Of The ‘703 Patent By**  
**Defendants Lupin and Lupin Pharma**

37. Lupin admits it submitted ANDA No. 90-051 to the FDA under §505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)), which seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride (“the Lupin Products”) for the treatment of moderate to severe dementia of the Alzheimer’s type, which is the only FDA approved use for memantine hydrochloride. Lupin admits that ANDA No. 90-051 seeks to market the Lupin products prior to the expiration of the ‘703 patent. To the extent there are remaining allegations in paragraph 37 of the Complaint, Lupin denies them.

38. Lupin admits that pursuant to §505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Lupin certified in ANDA No. 90-051 and its §505(j)(2)(A)(vii)(IV) statement (the “Paragraph IV statement”) that the claims of the ‘703 patent are invalid and/or not infringed by the commercial manufacture, use or sale of the Lupin products. Lupin admits that Plaintiffs received written notification of ANDA No. 90-051 and the Paragraph IV statement on or about December 14, 2007. To the extent there are remaining allegations in paragraph 38 of the Complaint, Lupin denies them.

39. Lupin denies that it has infringed any valid claim of the '703 patent under 35 U.S.C. § 271(e)(2)(A) by filing its ANDA No. 90-051, which seeks approval from the FDA to engage in commercial manufacture, use and sale of the Lupin products for the treatment of moderate to severe dementia of the Alzheimer's type, which is the only FDA approved use for memantine hydrochloride, prior to the expiration of the '703 patent. Lupin denies it would infringe the '703 patent under 35 U.S.C. §271(a), (b) and/or (c) if Lupin commercially manufactures, uses, offers to sell, sells, or imports any of the Lupin products for the treatment of moderate to severe dementia of the Alzheimer's type, which is the only FDA approved use for memantine hydrochloride, or if Lupin induces or contributes to any such conduct. To the extent there are remaining allegations in paragraph 39 of the Complaint, Lupin denies them.

40. Lupin Pharmaceuticals, Inc. denies that it has infringed any valid claim of the '703 patent, and therefore, denies any liability for any infringement of the '703 patent. Lupin Pharmaceuticals, Inc. admits that it participated in and contributed to Lupin Ltd.'s submission of ANDA No. 90-051 and its Paragraph IV statement to the FDA. Lupin denies the remaining allegations in paragraph 40 of the Complaint.

41. Lupin Pharma denies the allegations in paragraph 41 of the Complaint.

42. Lupin admits that it was aware of the '703 patent prior to filing ANDA No. 90-051.

43. Lupin denies the allegations in paragraph 43 of the Complaint.

44. Lupin denies the allegations in paragraph 44 of the Complaint.



**Count III – Infringement of the ‘703 Patent By Defendants Orchid and Orchid Pharma**

45. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 45 of the Complaint.

46. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 46 of the Complaint.

47. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 47 of the Complaint.

48. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 48 of the Complaint.

49. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 49 of the Complaint.

50. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 50 of the Complaint.

51. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 51 of the Complaint.

52. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 52 of the Complaint.

**Count IV – Infringement Of The ‘703 Patent By Defendant Teva**

53. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 53 of the Complaint.

54. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 54 of the Complaint.

55. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 55 of the Complaint.

56. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 56 of the Complaint.

57. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 57 of the Complaint.

58. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 58 of the Complaint.

**Count V – Infringement Of The ‘703 Patent By Defendant Upsher-Smith**

59. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 59 of the Complaint.

60. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 60 of the Complaint.

61. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 61 of the Complaint.

62. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 62 of the Complaint.

63. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 63 of the Complaint.

64. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 64 of the Complaint.

**Count VI – Infringement Of The ‘703 Patent By Defendants Wockhardt  
And Wockhardt USA**

65. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 65 of the Complaint.

66. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 66 of the Complaint.

67. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 67 of the Complaint.

68. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 68 of the Complaint.

69. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 69 of the Complaint.

70. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 70 of the Complaint.

71. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 71 of the Complaint.

72. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 72 of the Complaint.

73. Lupin further answers that any allegations in the Complaint requiring a response from Lupin not specifically admitted or denied are hereby denied. Lupin also denies that Plaintiffs are entitled to the judgment and relief prayed for in paragraphs (A) through (F) of the Complaint.

### **AFFIRMATIVE DEFENSES**

Further responding to the Complaint, and as additional defenses thereto, Lupin asserts the following affirmative defenses, without admitting any allegations of the Complaint not otherwise admitted and without assuming any burden when such burden would otherwise be on Plaintiffs.

#### **FIRST AFFIRMATIVE DEFENSE** **(Invalidity of the '703 Patent)**

74. In view of the allegations of infringement contained in the Complaint, one or more of the claims of the '703 patent are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. § 101 *et seq.* By way of example and not of limitation, any claim construed so as to be infringed by Lupin would be invalid under 35 U.S.C. §§ 112 and 305.

#### **SECOND AFFIRMATIVE DEFENSE** **(Non-infringement of the '703 Patent)**

75. The manufacture, use, offer for sale, sale, or importation of the Lupin products that are the subject of ANDA No. 90-051 does not and will not infringe any claim of the '703 patent, either literally or under the doctrine of equivalents.

**THIRD AFFIRMATIVE DEFENSE**  
**(Failure to State a Claim)**

76. To the extent that Plaintiffs allege that Lupin has infringed or will infringe the '703 patent, or that this case is exceptional under 35 U.S.C. § 285, the Complaint fails to state a claim upon which relief can be granted and must be dismissed.

77. To the extent that Plaintiffs allege that the Notice Letter and/or the Detailed Statement contained therein is deficient, the Complaint fails to state a claim upon which relief can be granted and must be dismissed.

**COUNTERCLAIMS**

Further responding to the Complaint, Lupin alleges the following counterclaims, without admitting any allegations of the Complaint not otherwise admitted and without assuming the burden when such burden would otherwise be on Plaintiffs.

**THE PARTIES**

78. Lupin Ltd. is an Indian corporation having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

79. Lupin Pharmaceuticals, Inc. is a Virginia corporation having a principal place of business at Harborplace Tower, 111 S. Calvert Street, 21<sup>st</sup> Floor, Baltimore, Maryland 21202 (referred to herein, together with Lupin Ltd., as "Lupin").

80. Upon information and belief, based on the allegations of the Complaint, Counter-Defendant Forest Laboratories, Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

81. Upon information and belief, based on the allegations of the Complaint, Counter-Defendant Forest Laboratories Holdings, Ltd. Is an Irish corporation having a principal place of business at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda (referred to herein, together with Forest Laboratories, Inc., as “Forest”).

82. Upon information and belief, based on the allegations of the Complaint, Counter-Defendant Merz Pharma GmbH & Co. KGaA is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany.

83. Upon information and belief, based on the allegations of the Complaint, Counter-Defendant Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany (referred to herein, together with Merz Pharma GmbH & Co. KGaA as “Merz”).

84. Upon information and belief, based upon the assertions made by the Plaintiffs and Counter-Defendants in their Complaint, Merz is the owner of United States Patent No. 5,061,703 (“the ‘703 patent”), entitled “Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia” a copy of which, with its Reexamination Certificate dated November 7, 2006, is attached hereto as Exhibit A.

85. Upon information and belief, based upon the assertions made by the Plaintiffs and Counter-Defendants in their Complaint, Forest is the exclusive licensee of the ‘703 patent in the United States and Forest holds New Drug Application (“NDA”) No. 21-487 for Namenda® brand memantine hydrochloride tablets.

**JURISDICTION AND VENUE**

86. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq.*

87. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that the '703 patent is invalid and is not infringed.

88. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391.

**THE CONTROVERSY**

89. Lupin holds Abbreviated New Drug Application ("ANDA") No. 90-051 for tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride (the "Lupin Products").

90. On or about January 10, 2008, Plaintiffs and Counter-Defendants filed the present action against Lupin alleging infringement of the '703 patent arising from Lupin's submission of ANDA No. 90-051.

**COUNTERCLAIM COUNT I**  
**(Declaratory Judgment Of Non-infringement)**

91. Lupin repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

92. Lupin's commercial manufacture, use, offer for sale, sale, or importation of the Lupin Products that are the subject of ANDA No. 90-051 will not infringe any claim of the '703 patent.

93. Because Lupin has not infringed and will not infringe any claim of the '703 patent, Plaintiffs and Counter-Defendants are entitled to no damages or other relief from or against Lupin.

**COUNTERCLAIM COUNT II**  
**(Declaratory Judgment Of Invalidity)**

94. Lupin repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

95. In view of the allegations of infringement contained in the Complaint, one or more of the claims of the '703 patent are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. § 101 *et seq.* By way of example and not of limitation, any claim construed so as to be infringed by Lupin would be invalid under 35 U.S.C. §§ 112 and 305.

**COUNTERCLAIM COUNT III**  
**(Order To Delist The '703 Patent from The Orange Book)**

96. Lupin repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

97. Forest's NDA No. 21-487 for Namenda<sup>®</sup> brand memantine hydrochloride tablets is approved by the Food and Drug Administration ("FDA") for the treatment of moderate to severe dementia of the Alzheimer's type.

98. The '703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Namenda<sup>®</sup> brand memantine hydrochloride tablets.



99. The '703 patent does not claim a method for the treatment of moderate to severe dementia of the Alzheimer's type, and, therefore does not claim an approved method of using memantine hydrochloride.

100. Pursuant to 21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb), Plaintiffs and Counter-Defendants must delist the '703 patent from the Orange Book for Namenda<sup>®</sup> brand memantine hydrochloride tablets and correct the patent information in the Orange Book for Namenda<sup>®</sup> brand memantine hydrochloride tablets. The Court has the power, pursuant to 21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb), to enter an order requiring the holder of the NDA to correct or delete reference to the '703 patent, as patent information submitted by the NDA holder under 21 U.S.C. §355(b).

#### **PRAYER FOR RELIEF**

WHEREFORE, Lupin respectfully requests the Court enter judgment against Plaintiffs and Counter-Defendants to include:

(a) A declaration that Lupin's submission of ANDA No. 90-051 seeking FDA approval to market the 5 mg and 10 mg memantine hydrochloride tablets described therein prior to the expiration of the '703 patent has not infringed, and will not infringe, any claim of the '703 patent;

(b) A declaration that Lupin's commercial manufacture, use, offer for sale, sale, or importation of its 5 mg and 10 mg memantine hydrochloride tablets will not infringe any claim of the '703 patent;

(c) A declaration that the claims of the '703 patent are invalid;

(d) A declaration that Plaintiffs and Counter-Defendants are entitled to no damages, interest, costs, or other relief from or against Lupin for infringement of the '703 patent pursuant to 35 U.S.C. § 271(e)(4)(C), or any other provision of law;

(e) A declaration that Plaintiffs and Counter-Defendants are entitled to no damages, interest, costs, or other relief from or against Lupin for infringement of the '703 patent pursuant to 35 U.S.C. §§ 283 through 285, or any other provision of law;

(f) An order pursuant to 21 U.S.C. §355(c)(3)(D)(ii)(I)(bb) requiring Plaintiffs and Counter-Defendants to delist the '703 patent from the Orange Book for Namenda® brand memantine hydrochloride tablets and to correct the patent information in the Orange Book for Namenda® brand memantine hydrochloride tablets.

(g) Such other and further relief as the Court deems just and proper.

February 4, 2008

BAYARD, P.A.

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**CERTIFICATE OF SERVICE**

The undersigned counsel certifies that, on February 4, 2008, he electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

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The undersigned counsel further certifies that, on February 4, 2008, copies of the foregoing document were sent by email and hand to the above local counsel and by email and first class mail to the following non-registered participant:

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